UNITED STATES PATENT AND TRADEMARK OFFICE

NOV 25 2009

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

James V. Lilly
Kagan Binder, PLLC
221 Main St. North, Suite 200
Stillwater, MN 55082

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,336,263

NOTICE OF FINAL DETERMINATION AND REQUIREMENT FOR ELECTION

A determination has been made that U.S. Patent No. 5,336,263, which claims a method of using the medical device Macroplastique® Implants, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,664 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period.

Applicant also has applied for patent term extension of U.S. Patent Nos. 5,258,028 and 5,711,182 based on the regulatory review period for the medical device, Macroplastique® Implants, PMA P040050. .

When patent term extension applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension is issued to the patent having the earliest date of issuance, unless applicant elects a different patent. In the absence of an election by applicant within one month of the date of this notice, and in accordance with 37 CFR 1.785(b), the applications for patent term extension in U.S. Patent Nos. 5,336,263 and 5,711,182 will be denied. Accordingly, the application for patent term extension of the patent having the earlier date of issuance will be granted. That is, a certificate of extension will be issued to U.S. Patent No. 5,258,028 for a period of 1,664 days. In the absence of a single request for reconsideration as to the length of extension of the patent and, if U.S. Patent No. 5,336,263 is elected, the Director will issue to the applicant a certificate of extension, under seal, for a period of 1,664 days in U.S. Patent No. 5,336,263.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of February 11, 2009, (74 Fed. Reg. 6901). Under 35 U.S.C. § 156(c):

Period of Extension	=	½ (Testing Phase) + Approval Phase
	=	½ (1,973) + 678
	=	1,664 days (4.6 years)

Since the regulatory review period began July 30, 1999, after the patent issued (August 9, 1994),

the entire regulatory review period has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,336,263
Granted:	August 9, 1994
Original Expiration Date[1]:	April 6, 2012
Applicant:	Robert A. Ersek et al.
Owner of Record:	Uroplasty, Inc.
Title:	Treatment of Urological and Gastric Fluid Reflux Disorders by Injectin of Microparticles
Product Trade Name:	Macroplastique® Implants
Term Extended:	1,664 days
Expiration Date of Extension:	October 26, 2016

[1]Subject to the provisions of 35 U.S.C. § 41(b).

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: Macroplastique® Implants
FDA Docket No.: FDA-2008-E-0099